

**L-TOPICAL BENZOYL PEROXIDE 5% GEL- benzoyl peroxide gel**  
**GLOBAL PHARMA HEALTHCARE PRIVATE LIMITED**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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**L-Topical BENZOYL PEROXIDE 5% GEL**

**DRUG FACTS**

**Active ingredient**

Benzoyl peroxide 5%

**Purpose**

Acne treatment

**Use**

For the treatment of acne

**Warnings**

**For external use only**

**Do not use** if you • Have very sensitive skin • Are sensitive to benzoyl peroxide

**When using this product** • Skin irritation and dryness is more likely to occur if you use another topical acne medication at the same time. If irritation occurs, only use one topical acne medication at a time. • Avoid unnecessary sun exposure and use a sunscreen • Avoid contact with the eyes, lips, and mouth • Avoid contact with hair and dyed fabrics, which may be bleached by this product • Skin irritation may occur, characterized by redness, burning, itching, peeling, or possibly swelling. Irritation may be reduced by using the product less frequently or in a lower concentration.

**Stop use and ask a doctor if** irritation becomes severe.

**KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.**

If swallowed, get medical help or contact a Poison Control Center immediately.

**Directions**

• Clean the skin thoroughly before applying this product • Cover the entire affected area with a thin layer and rinse thoroughly one to three times daily • Because excessive drying of the skin may occur, start with one application daily, then gradually increase to two or three times daily if needed or as directed by a doctor • If bothersome dryness or

peeling occurs, reduce application to once a day or every other day. • If going outside, apply sunscreen after using this product. If irritation or sensitivity develops, stop use of both products and ask a doctor.

## Other information

Store at 15°-30°C (59°-86°F).

## Inactive ingredients

Allantoin, Aloe barbadensis leaf extract, Benzyl alcohol, Carbomer, Disodium EDTA, Disodium laureth sulfosuccinate, Glycerin, Panthenol, PEG-8, PPG-14 palmeth-60 hexyl dicarbamate, Sodium hyaluronate, Triethanolamine, Water

## Questions?

Call toll-free 1-800-572-6632, Weekdays 7:00 AM - 5.30 PM EST.

## ✓ Acne Treatment

Manufactured by :

**Global Pharma Healthcare Pvt. Ltd.,**

A-9, SIDCO Pharmaceutical Complex,

Alathur-603 110 - INDIA.

**[www.global-pharma.com](http://www.global-pharma.com)**

## Packaging

<b>DRUG FACTS</b>	NDC 73921-031-04	<b>L-Topical</b>	application to once a day or every other day. ■ If going outside, apply sunscreen after using this product. If irritation or sensitivity develops, stop use of both products and ask a doctor.
<b>Active ingredient</b> Benzoyl peroxide 5%	<b>Purpose</b> Acne treatment		<b>Other information</b> Store at 15°-30°C (59°-86°F).
<b>Use</b> For the treatment of acne			<b>Inactive ingredients</b> Allantoin, Aloe barbadensis leaf extract, Benzyl alcohol, Carbomer, Disodium EDTA, Disodium laureth sulfosuccinate, Glycerin, Panthenol, PEG-8, PPG-14 palmeth-60 hexyl dicarbamate, Sodium hyaluronate, Triethanolamine, Water
<b>Warnings</b> <b>For external use only</b> <b>Do not use</b> if you ■ Have very sensitive skin ■ Are sensitive to benzoyl peroxide <b>When using this product</b> ■ Skin irritation and dryness is more likely to occur if you use another topical acne medication at the same time. If irritation occurs, only use one topical acne medication at a time. ■ Avoid unnecessary sun exposure and use a sunscreen ■ Avoid contact with the eyes, lips, and mouth ■ Avoid contact with hair and dyed fabrics, which may be bleached by this product ■ Skin irritation may occur, characterized by redness, burning, itching, peeling, or possibly swelling. Irritation may be reduced by using the product less frequently or in a lower concentration. <b>Stop use and ask a doctor</b> if irritation becomes severe.			<b>Questions?</b> Call toll-free 1-800-572-6632, Weekdays 7:00 AM - 5.30 PM EST.
<b>KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.</b> If swallowed, get medical help or contact a Poison Control Center immediately.			
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<b>BENZOYL PEROXIDE 5% GEL</b>			
✓ Acne Treatment			
Global Pharma 4 FL OZ (118ml)			
		Mfg. Lic. No. : TN 00002175	
		Batch No. :	
		Mfg. Date :	
		Exp. Date :	
		Manufactured by : Global Pharma Healthcare Pvt. Ltd., A-9, SIDCO Pharmaceutical Complex, Alathur-603 110 - INDIA. <a href="http://www.global-pharma.com">www.global-pharma.com</a>	

**L-TOPICAL BENZOYL PEROXIDE 5% GEL**

benzoyl peroxide gel

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:73921-031
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>BENZOYL PEROXIDE</b> (UNII: W9WZN9A0GM) (BENZOYL PEROXIDE - UNII:W9WZN9A0GM)	BENZOYL PEROXIDE	50 mg in 1 mL

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>ALLANTOIN</b> (UNII: 344S277G0Z)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>BENZYL ALCOHOL</b> (UNII: LKG8494WBH)	
<b>CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE</b> (UNII: 0A5MM307FC)	
<b>EDETATE DISODIUM ANHYDROUS</b> (UNII: 8NLQ36F6MM)	
<b>DISODIUM LAURETH SULFOSUCCINATE</b> (UNII: D6DH1DTN7E)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>PANTHENOL</b> (UNII: W9CM0067Z)	
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	
<b>PPG-14 PALMETH-60 HEXYL DICARBAMATE</b> (UNII: 376C96Y6AL)	
<b>HYALURONATE SODIUM</b> (UNII: YSE9PPT4TH)	
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	
<b>WATER</b> (UNII: 059QF0KO0R)	

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
<b>1</b>	NDC:73921-031-04	118 mL in 1 CONTAINER; Type 0: Not a Combination Product	04/01/2021	

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph final	part333D	04/01/2021	

**Labeler -** GLOBAL PHARMA HEALTHCARE PRIVATE LIMITED (860186917)

**Establishment**

Name	Address	ID/FEI	Business Operations
GLOBAL PHARMA HEALTHCARE PRIVATE LIMITED		860186917	manufacture(73921-031)

Revised: 3/2021

GLOBAL PHARMA HEALTHCARE PRIVATE LIMITED